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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,108	02/10/2004	Charles R. Ashby JR.	BSA 04-09	2666

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BROOKHAVEN SCIENCE ASSOCIATES/
BROOKHAVEN NATIONAL LABORATORY
BLDG. 475D - P.O. BOX 5000
UPTON, NY 11973

EXAMINER	
LEWIS, AMY A	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/776,108	ASHBY, CHARLES R.	
	Examiner	Art Unit	
	Amy A. Lewis	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,10 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,10 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Case

The examiner for the instant application has changed. The current examiner assigned to this application is Amy A. Lewis.

The Amendments and Remarks filed 24 January 2006, have been entered into the application. Claim 15 has been amended. Claims 9, 10, and 15, as filed 24 January 2006, are presently examined.

Rejection of claims 9, 10, and 15 under 35 U.S.C. 112, second paragraph, as being indefinite has been ***withdrawn*** in view of Applicant's amendments.

NEW GROUNDS OF REJECTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1) Claims 9, 10 and 15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,713,497 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both teach a composition of vitamin B6 and the GABAergic drug gamma vinyl GABA (GVG). While the 6,713,497 patent is directed to a method of treatment, a method of using a compound renders the compound itself obvious. Therefore the current application is an obvious varation of the 6,713,497 patent claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2) Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Blum et al. (US Patent No. 5189064).

Blum teaches a composition which contains amino acids and analogs of GABA and GABA precursors (see: claim 10). Blum teaches an Example of an amino acid formulation containing L-glutamine and pyridoxal phosphate (i.e., vitamin B6) (see

Example 1, col. 17, lines 1-20). Applicant defines a GABAergic drug to be a drug known to increase GABA levels in the brain (see specification p. 1, lines 8-9). Thus, the formulation of Blum's Example 1 meets the limitations of claim 9.

3) Claim 9 is rejected under 35 U.S.C. 102(a) as being anticipated by Evans et al. (US Patent Application Pub. No. 2002/0048612 A1).

Evans teaches a composition with contains a GABA substrate and various vitamins and cofactors. The reference teaches that absorption of the claimed compounds containng butyrates formulated with promoters, promotes transfiguration to GABA and to raise the levels of GABA in the brain (p. 2, paragraphs [0019-0020]. The GABA substrates of Evans meet the definition of GABAergic drugs, according to the definition in Applicant's specification (see specification p. 1 lines 8-9).

Evans teaches a specific Example of a composition containing vitamin B6, magnesium butyrate, and calcium butyrate (Table 1 on p. 3). Applicant defines a GABAergic drug to be a drug known to increase GABA levels in the brain (see specification p. 1, lines 8-9). Thus, the formulation of Table 1 meets the limitations of claim 9.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4) Claims 9, 10, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blum et al. (US Patent No. 5189064).

Blum teaches a composition which contains amino acids and analogs of GABA and GABA precursors (see: claim 10). Blum teaches an Example of an amino acid formulation containing L-glutamine and pyridoxal phosphate (i.e., vitamin B6) (see Example 1, col. 17, lines 1-20). Applicant defines a GABAergic drug to be a drug known to increase GABA levels in the brain (see specification p. 1, lines 8-9). Thus the formulation of Blum's Example 1 meets the limitations of claim 9.

In addition, Blum teaches that the main synthetic pathway to GABA is via decarboxylation of L-glutamic acid by the enzyme glutamic acid decarboxylase (GAD), which needs vitamin B6 as a cofactor in order to function. Blum also teaches that L-glutamine contributes to the maintenance of the inhibitory neurotransmitter GABA (col. 15, lines 27-35). Blum also teaches that GABA is metabolized by the enzyme GABA animotransferase (GABA-T), which also requires vitamin B6 as a cofactor in order to function (col. 16, lines 31-45). The reference also teaches that administration to animals

of the drug the drug gamma vinyl GABA (GVG) inhibits GABA-T and increases GABA concentrations (col. 16, lines 47-55).

Blum does not specifically teach a composition containing GVG and vitamin B6.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a composition containing GVG and vitamin B6. The skilled artisan would have been motivated to make such a composition, with a reasonable expectation of success, having been taught by Blum that GVG and vitamin B6 increase GABA concentrations. The skilled artisan would have been further motivated by the fact that vitamin B^ works to increase GABA concentration sat two points along the synthetic pathway, i.e. as factors for GAD and GABA-T (as taught by Blum). Therefore, the invention as a whole would have been prima facie obvious.

Conclusion

Claims 9, 10 and 15 are rejected. No claims are allowed. This rejection is made NON-FINAL due to the new grounds of rejection.

Contact Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is (571) 272-2765. The examiner can normally be reached on Monday-Friday, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy A. Lewis
Patent Examiner
Art Unit 1614

Ardin Marschel
SPE
Art Unit 1614

Ardin H. Marschel 5/14/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER